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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/056,807 | 01/25/2002 | Jon Ocel | M190.134.101 | 9381 |

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EXAMINER

VRETTAKOS, PETER J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3739 | |

DATE MAILED: 04/23/2003

A

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/056,807 | OCEL ET AL. |
| Examiner | Art Unit | |
| Peter J Vrettakos | 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 January 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Applicant is requested to disclose the material that makes up the shaft, allowing it to “independently” maintain its shape.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant neglects to adequately disclose the characteristics and materials that constitute the shaft, which permit it to “independently” maintain its bent shape.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner cannot construe the meaning of the language, “the rigid coupling... the tip is readily manipulated in a sliding fashion via movement of the handle,” and further is not enabled from the disclosure in the Specification. The

Examiner reserves the right to apply a substantive rejection subsequent to clarification by the Applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11, 13-18, 24-31, and 33-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hovda et al. ('172).

Hovda et al. (Hovda) discloses an electrosurgical instrument (10) as part of a system (11) and a method of use comprising:

an elongated shaft (100) with a proximal section, a distal section with a rounded tip (102), and an internal lumen (233, col. 17:28-37) , and further wherein the shaft is adapted to be transitionable from a straight state to a first bent state, the shaft independently maintaining distinct shapes (col. 11:30-35 and col. 18:1-11).

Hovda also discloses a handle (204) and an exterior (18, col. 21:62-64) of the shaft that is electrically non-conductive.

Hovda further discloses a source (21) of conductive fluid and an energy source (28). See column 15:41-45.

Note: although the figures in Hovda neglect to depict a rounded tip, Hovda, indeed discloses that the shape of the electrodes (which dictate the shape of the tip)

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can be round (col. 28:6). Also see col. 13:39-43 ("hemispherical" describes a rounded tip).

Further, with regards to the Applicant's method claims, two distinct bends are possible in Hovda that is depicted in figure 2. They are the bend at element 101 and the bend at element 104. Both bends are capable of independently maintaining their shapes.

Re: claims 2,3,4: Hovda discloses equidistally-aligned passages (209, fig. 3 or 83, fig. 7c). In figure 7c there are two sets of circumferentially aligned passages (designated by the Examiner as "center" adjacent to inner element 112 and "peripheral" adjacent to outer element 112).

Re: claims 7,8, 9,10, 27,28, and 29, note Hovda (col. 11:30-37 and col. 18:1-11). "Bend angles" as disclosed by the Applicant are the angle the shaft is bent with respect to the linear axis defined by the straightened shaft.

Re: claims 11, 30, 40, see column 7:9-18.

Re: claims 13,14, 31, 32: Hovda discloses an elongate electrode body (104, fig. 4) directly coupled (250, fig. 5) to the handle (204, fig. 2). See column 19: 30-32. The electrodes are electrically insulated (col. 12:18-27, element 102, column 20: 31-34). Further, the electrode body is inherently malleable. If the body was not malleable, during the pre-surgical manipulation of the instrument (as referred to in col. 11:29-37) to suit the surgical application, the body would break.

Re: claim 15. the insulator (102) is configured to conform to the electrode body in the straight and first bent state (col. 20: 31-36).

Re: claims 16,17,18, Hovda discloses an elongated tube (100) that can be either conductive or non-conductive (col. 17:1-5).

Re: claim 20, Hovda discloses a joint ("bend", col. 17:45-47) that can be controlled by a remote actuator (pull-wire, col. 17:53-59). **Note: this pull-wire disclosure does not mean that a pull-wire is required for the Hovda device to independently maintain distinct bent shapes, thereby voiding the rejection.** (The Applicant in page 12 lines 11-14 of the instant Specification discloses that the ability to independently maintain a distinct bent shape indicates that a pull-wire or an additional component is not present.) The pull wire asserted in Hovda is for distal control of the device tip but is not required for the device to maintain a distinct bent shape along the device shaft.

Re: claim 26, the presence or lack thereof a discernable drag direction is inherent to the design of the Hovda device.

Re: claim 33,34,35,36, Hovda discloses conductive fluid and energy source switches (col. 12:37-41; 17, 30, 37-39, figure 1; col. 15:65-67, col. 16:1-5, col. 17:42-44).

Re: claims 37and 38, Hovda discloses a sensor (sensing electrode) in column 9 line 62 through column 10 line 8 and an indicator light (fiber optic head light) attached to the instrument in column 15: 45-49.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-16, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Panescu et al. ('267).

Hovda neglects to **expressly** disclose a tip with a uniform radius of curvature.

Panescu discloses an electrosurgical instrument with a rounded tip in figure 2a that is nearly identical (geometrically, structurally) to that disclosed by the Applicant. As a result the Applicant's claims with regards to discernible drag and other operational or structural characteristics (ex. uniform radius of curvature) of the instant invention are made obvious.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Panescu by including a rounded device tip. The motivation to substitute the device tip in Hovda with that in Panescu would be to improve cooling of the tip electrode as posited in Panescu column 6:23-26, as well as to permit lateral (with respect to the linear axis of the shaft) energy application in addition to forward or longitudinal application.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Moaddeb et al. ('078).

Hovda neglects to **expressly** disclose gluing the distal tip of the instrument to the elongated shaft.

Moaddeb et al. discloses an analogous electrosurgical instrument in which gluing the distal tip to the elongated shaft is submitted in column 6:26-28.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hovda in view of Moaddeb by including an analogous electrosurgical instrument in which gluing the distal tip to the elongated shaft is disclosed. The clear motivation would be to prevent the device from falling apart.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cox et al. ('543).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
April 21, 2003

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Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER